

The National Children's Study

U.S. Department of Health and Human Services

National Institute of Child Health and Human Development

National Institute of Environmental Health Sciences

Centers for Disease Control and Prevention

U.S. Environmental Protection Agency



HEALTH GROWTH ENVIRONMENT



What is the National Children's Study?

- The National Children's Study (Study) is the largest long-term study of children's health and development ever to be conducted in the U.S.
- *Longitudinal study*—meaning it will study the same group of children, their families, and their environment over an extended period of time (21 years or longer, from before birth)
- Study common range of “environmental” exposures and less common outcomes in 100,000 participants
- Examine genetic factors and expression
- Environment defined broadly—chemical, physical, behavioral, social, and cultural





Why Is the Study Important?

- Between 1980 and 1995, the percentage of children with asthma doubled
- The proportion of children aged 6-18 who were overweight increased from 6% in 1976-1980 to 15% in 1999-2000
- 3-8% of children born each year will be affected by a neurodevelopmental disorder
- Great disparities remain in infant mortality rates among ethnic groups





Why Conduct the Study Now?

- The Study is needed to identify effects or to assure safety
 - Children generally have an increased vulnerability to environmental exposures
 - Exposures to some agents have caused serious developmental effects (e.g., lead, alcohol)
 - There are known current exposures of high frequency (e.g., pesticides, phthalates)
- Longitudinal design will allow examination of multiple exposures and multiple outcomes
- Previous and existing studies have been limited in size & scope





Why Focus on Children?

Children have:

- Increased vulnerability to environmental exposures
- Critical windows of vulnerability during development
- Immature mechanisms for detoxification and protection
- Differences in metabolism and behavior that may yield higher exposure in the same environments





What Will be the Impact on Health & Research?

- The National Children's Study will identify not only what is harmful but what is helpful to children's health
- The data collected will become a national resource that has the potential to answer future questions that science has yet to ask





History of the National Children's Study



- President's Task Force on Environmental Health Risks and Safety Risks to Children (1998)
 - Charged with developing strategies to reduce risk of environmental exposures to children
 - Co-chaired by HHS Secretary and EPA Administrator
 - Additional members included seven cabinet officers and senior staff





History of the National Children's Study



- Conclusions of President's Task Force
 - Many risks to children are not clear or quantified
 - Need for additional study of effects of environmental exposures
 - Consultation in Jan. 2000 endorsed study: large, bold, multiple agencies, public-private partnerships
 - New money would be required to carry it out





Public Law 106-310: Children's Health Act of 2000



- **(a) PURPOSE - ... to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.**
- **(b) IN GENERAL -** The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to:
 - (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
 - (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes...
- **(e) AUTHORIZATION OF APPROPRIATIONS -** There are authorized to be appropriated to carry out this section \$18,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2002 through 2005.



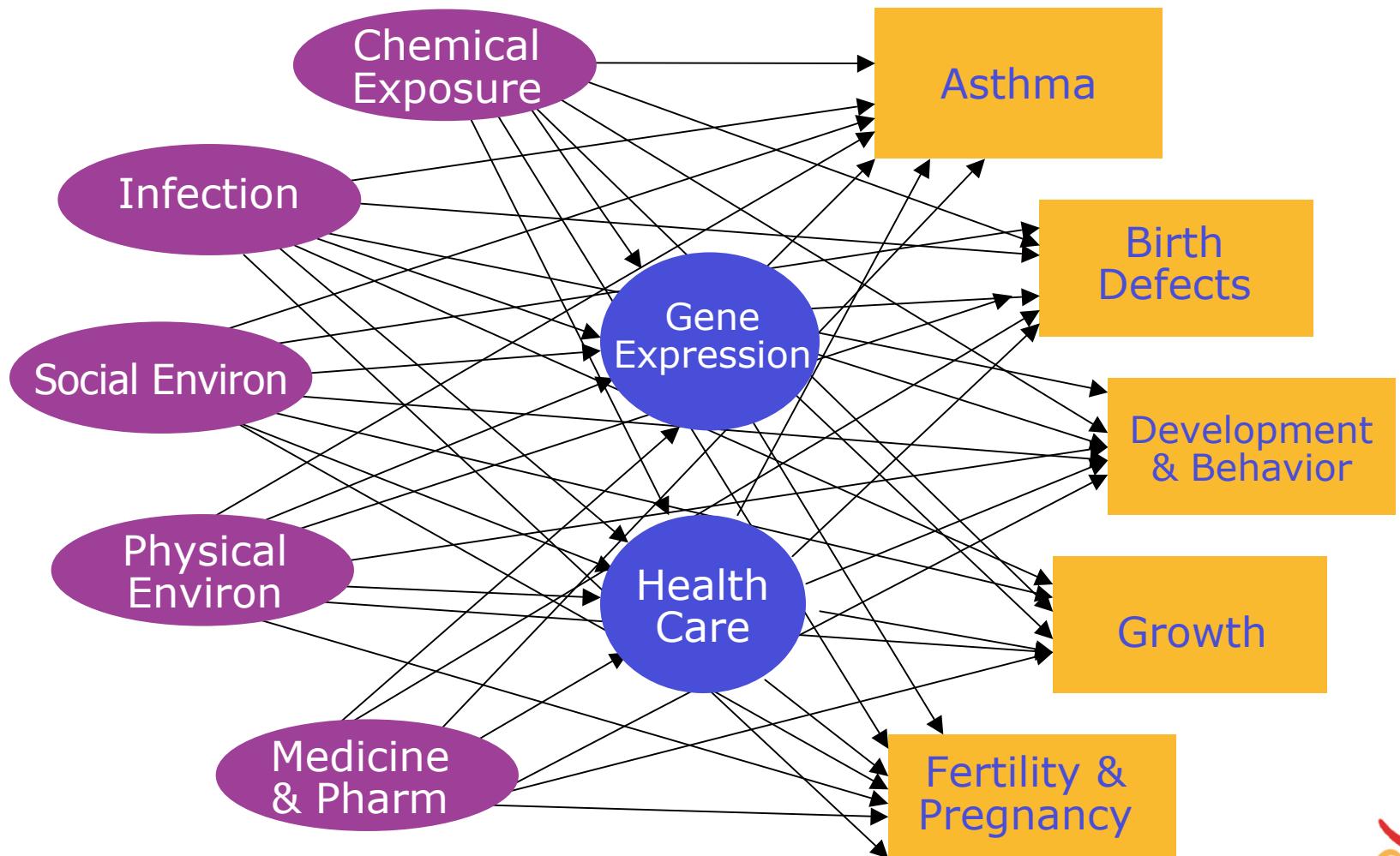


How Will the Study be Conducted?

- Using a longitudinal, representative sample of the U.S.
- Using state-of-the-art technology – tracking, measurement, data management
- Manage through a cooperative consortium of multiple agencies (U.S. EPA, HHS – NIH, CDC)
- Access extensive public-private partnerships
- Develop a national resource for future studies



Associations and Interactions





What Will the Study Provide?

- **Data to address concerns about exposure** to potential toxicants during childhood
- The **power to determine harmful, harmless, or beneficial effects** of exposures
- **Causal factors for a number of diseases** and conditions of children
- Information on how **multiple causes** interact to result in **multiple outcomes**





What Will The Study Provide?

- Large sample size required to **apply knowledge of the human genome** to understand multifactorial genetic conditions
- Identification of early life **factors that contribute to many adult conditions**
- A **national resource to answer future questions** by using stored biological and environmental samples and the extensive data for decades to come



Projected Study Time Line

as of 1/06



- 2000-present Pilot studies/methods development
- 2004 Developed Study Design and Study Plan
- 2004 Posted Requests For Proposals: Coordinating and Vanguard Centers
- 2005 Awarded initial contracts (Coordinating and Vanguard Centers)
- 2005-2007 Start-up phase for Vanguard Centers
- 2006 Completion of the Study protocol
- 2006-2007 Requisite reviews and approvals
- 2006-2007* Post Requests for Proposals for additional Study Centers
- 2008-2012* Enroll participants and begin the full Study at Vanguard Centers
- 2007* Award additional Study Centers (contracts)
- 2007-2008* Start-up phase for additional Study Centers
- 2009-2012* Enroll participants and begin full Study at additional centers
- 2009* First Study results become available
- 2013-2034* Hypothesis-specific data analysis; publish data; public-use datasets

* PENDING FUNDING FOR FY'07



Study Funding as of March 2006

- FY 00-06: ~\$50m from existing budgets of NICHD/EPA/CDC/NIEHS
 - Infrastructure: Study Plan; Coordinating Center and 7 Vanguard Study Centers...
 - Scientific development: 28 workshops, 20 scientific reviews, 16 pilot studies; hypotheses, exposure and outcome measures, protocol in progress...
- FY 07: \$69m required to implement the NCS on the current timeline as per Congress' direction (report language for FY06 appropriation)
 - No NCS funding in the President's FY 07 budget
- To conduct the full Study: FY 08-34
 - ~ \$100m/year for 26 years

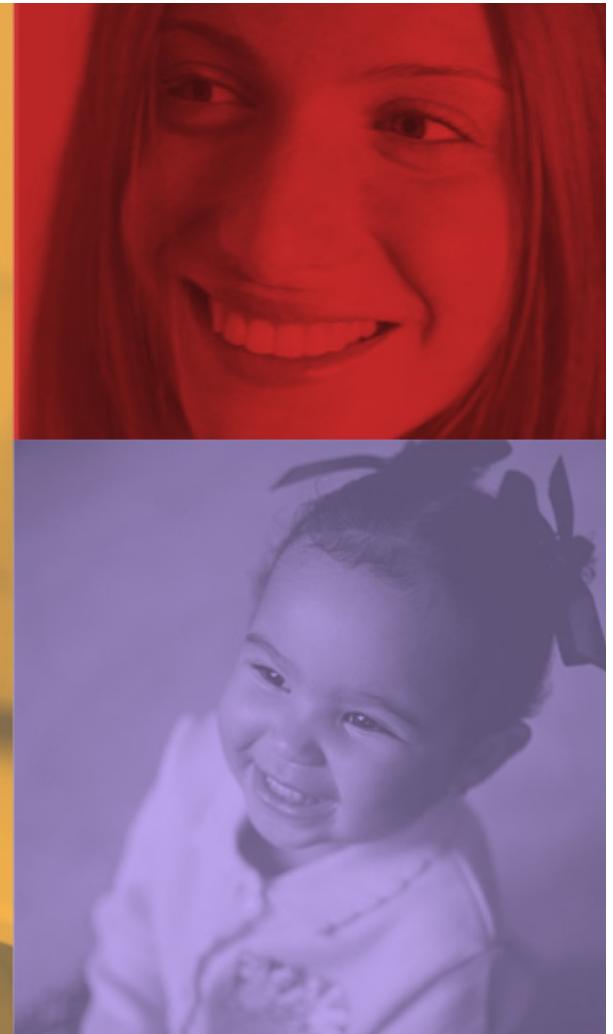




Contact Information

- Check the Web site:
<http://NationalChildrensStudy.gov>
- Join the listserv for news and communication (via the website)
- Contact us at ncs@mail.nih.gov





The End



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